CORNING CLINICAL LABORATORIES, INC.

CORPORATE INTEGRITY AGREEMENT

RECITALS

A. The parties to this Agreement are the United States Department of Health and Human Services ("HHS"), through the Office of Inspector General ("OIG"), Corning Clinical Laboratories, Inc. ("CCL") and Corning Nichols Institute ("CNI"), referred to herein collectively as "CCL/CNI".

B. CCL/CNI owns and operates a national system of clinical laboratories, draw stations, and patient services centers, including regional clinical laboratories in the following metropolitan areas: Atlanta, Georgia; Buffalo, New York; Cambridge, Massachusetts; Chicago, Illinois; Dallas, Texas; Deerfield Beach, Florida; Denver, Colorado; Billings, Montana; Horsham, Pennsylvania; Indianapolis, Indiana; Islip, New York; Auburn Hills, Michigan; Grand Rapids, Michigan; Nashville, Tennessee; Phoenix, Arizona; Pittsburgh, Pennsylvania; Baltimore, Maryland; San Juan Capistrano, California; St. Louis, Missouri; Tampa, Florida; Teterboro, New Jersey; Wallingford, Connecticut; Portland, Oregon; Lincoln, Nebraska; and San Diego, California.

C. CCL/CNI has entered into settlement agreements with the United States to address civil claims against CCL/CNI for certain conduct allegedly implicating the False Claims Act.

D. CCL/CNI wishes to demonstrate that it possesses the reliability, honesty, trustworthiness and high degree of business integrity expected of a participant in federally funded health care programs, and that it can be trusted to deal fairly and honestly with the Health Care Financing Administration ("HCFA") and the OIG.

E. In 1993, CCL/CNI formalized an internal compliance program, known as the "Legal Compliance Plan," with respect to its clinical laboratories, draw stations, and patient service centers nationwide. CCL/CNI agrees to maintain its Legal Compliance Plan and to take other actions, as specified herein, to assure the OIG that CCL/CNI possesses the high degree of honesty and business integrity required of a Medicare and Medicaid supplier.

AGREEMENT

Term

1. This Corporate Integrity Agreement ("Agreement") shall be in force and effect for five (5) years (the "Term"), commencing on the date this Agreement is executed by all the parties ("Execution Date").

Implementation and Purpose

2. CCL/CNI has implemented and agrees to maintain its Legal Compliance Plan ("LCP"), which was formally adopted in 1993, as it has been amended and is in effect as of the Execution Date. The LCP is hereby incorporated by reference into this Agreement. The terms of this Agreement are intended to complement and enhance CCL/CNI's LCP. CCL/CNI remains free to modify the LCP, as may be necessary to enhance its compliance efforts, and shall provide OIG notice of any modifications of the LCP within thirty (30) days after they are adopted.

3. The purpose of this Agreement is to enable CCL/CNI to demonstrate its integrity and honesty as a participant in federally funded health care programs and its compliance with the Applicable Laws defined below. Within ninety (90) days of the effective date of this Agreement, unless a longer period is specifically provided elsewhere in this Agreement, CCL/CNI will implement and maintain the requirements specified herein, including any and all changes and/or additions to the existing CCL/CNI LCP, to ensure, to the extent reasonably possible, that CCL/CNI and each of its corporate directors, officers, medical directors, and employees, as well as any individuals engaged directly by CCL/CNI as independent contractors in the sale, marketing, and billing of laboratory services, and all phlebotomists and other individuals involved in the ordering of laboratory services, maintain the business integrity and honesty required of a participant-supplier in federally funded health care programs, and that CCL/CNI is in compliance with this Agreement and all laws and regulations governing a provider's participation in federally-funded health care programs, including, but not limited to: Title XVIII of the Social Security Act, 42 U.S.C. Sections 1395-1395ccc (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. Sections 1396 et seq. (the Medicaid statute); the Medicare Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b); the False Claims Act, 31 U.S.C. Sections 3729 et seq. (as amended); the Program Fraud Civil Remedies Act, 31 U.S.C. Sections 3801 et seq.; the federal Anti-Kickback Act, 42 U.S.C. Sections 52 et seq.; and the Civil Monetary Penalties Law, 42 U.S.C. Sections 1320a-7a and 1320a-7b; and all applicable implementing regulations (hereafter "Applicable Laws"). The CCL/CNI LCP and the requirements of this Agreement will cover all CCL/CNI directors, officers, medical directors, employees, and those individuals engaged directly by CCL/CNI as independent contractors in the sale, marketing or billing of lab services and all phlebotomists and other individuals involved in the ordering of laboratory services.

4. Within 180 days after the Execution Date of this Agreement, the Vice President - Compliance and Government Affairs for CCL/CNI shall meet with OIG representatives to discuss implementation of this Agreement.

Program Enhancements

5. CCL/CNI acknowledges that every physician should be able to order only those clinical laboratory tests which the physician believes are medically appropriate for each individual patient. In order to reaffirm its commitment to this goal, CCL/CNI agrees to take the

following actions within the time periods reflected below or such longer period of time as may be necessary for CCL/CNI, in good faith, to implement these changes. CCL/CNI will notify OIG in writing upon completion of these actions. Failure to implement the following actions will constitute a material breach of this Agreement unless OIG has been apprised of CCL/CNI's difficulty in implementing a particular action within the prescribed time period and OIG is satisfied that CCL/CNI is making a good faith effort and taking reasonable action to implement such action promptly. Within thirty (30) days after receiving from CCL/CNI written notice of its difficulty in complying with the terms set forth below and the reasons therefor, OIG shall advise CCL/CNI in writing as to whether and how much relief it will grant CCL/CNI.

a. Revision of Non-Customized Test Offerings and General Requisition Forms.

(1) Within twelve (12) months of the Execution Date of this Agreement, CCL/CNI agrees to revise its noncustomized test offerings so that all such test offerings will be standard across the Company. CCL/CNI agrees to provide OIG and HCFA a listing of the revised non-customized test offerings and sample requisition forms prior to implementation within the Company. CCL/CNI agrees that OIG and HCFA are under no obligation to respond to or comment on the revised non-customized test offerings or requisition forms. The revised non-customized test offerings will emphasize physician choice and will encourage physicians to order only those tests which the physician believes are medically appropriate for each patient. With respect to chemistry tests, CCL/CNI will revise its non-customized test offerings so that chemistry tests must be ordered separately except: (a) where the test is specifically part of a HCPCS defined automated multichannel test series (e.g., 80002-80019), (b) where the test is part of a CPT-defined "clinically relevant test grouping" such as an organ or disease panel or profile (e.g., 80050 et seq.), or (c) where the chemistry test is part of a profile which has been customized at the request of the physician.

(2) CCL/CNI represents that it has initiated an aggressive plan to transition to a common set of test order and result codes to be used at all CCL/CNI laboratories, which will allow the use of a common general requisition form and reference manual by every CCL/CNI laboratory. CCL/CNI represents that test codes are used in every functional area of the CCL/CNI laboratory business, and that changing such codes must be done using carefully planned processes and rigorous quality control. Currently, CCL/CNI has 20 different sets of test order codes, 9 billing systems, 12 laboratory information systems, and 11 internal electronic order entry systems. The codes must be changed in hundreds of computer programs throughout the Company. CCL/CNI represents that it will have all of its customers transitioned to use of standard test codes, and that a common general requisition form will be used by all CCL/CNI laboratories, within 18 months of the Execution Date of this Agreement.

(3) In addition to revising its non-customized test offerings and general requisition forms as outlined in subsection (a)(1), above, CCL/CNI will include on all of its requisition forms, including those requisition forms prepared specially for physicians who request a customized profile, a printed reminder that when ordering tests for which Medicare or

Medicaid reimbursement will be sought, physicians should only order tests medically necessary for the diagnosis or treatment of the patient.

b. Interim Review of Standard Chemistry Profiles. Until such time as CCL/CNI implements its new requisition forms, as described in subparagraph 5.a.(1), above, CCL/CNI agrees that it will review each basic chemistry profile offering (Chem Screen Profile and Chem Panel Profile) for availability of physician choice and adequacy of disclosure. CCL/CNI agrees to advise OIG and HCFA of any changes made to its standard chemistry profile offerings within thirty (30) days after implementation of any such change. The Interim Review of Standard Chemistry Profiles shall be conducted within six (6) months of the Execution Date of this Agreement. In the event that CCL/CNI is unable to implement its new requisition forms within the time period described in subparagraph 5.a.(1), a second Interim Review of Standard Chemistry Profiles shall be conducted within twelve (12) months of the Execution Date of this Agreement.

c. Test Utilization Data. In order that the parties may determine whether any over-utilization of tests has occurred during the preceding year, CCL/CNI agrees to report to OIG, on an annual basis, claims submission data by CPT or HCPCS code for the top 30 tests performed at each lab for Medicare and Medicaid beneficiaries, and, beginning with the report due January 31, 1999, a calculation of the percentage of growth, if any, of each such test during the preceding calendar year. Beginning with the report due January 31, 1999, CCL/CNI also will report to OIG its overall growth in the total number of claims submitted for Medicare and Medicaid beneficiaries, if any, during the preceding calendar year. Such reports shall be due no later than January 31 of the year following the calendar year at issue, with the first such report on the top 30 tests performed at each lab due on January 31, 1998. Where the reports required above reveal that the growth in submitted claims for a particular test is significantly higher than the company's overall total growth in submitted claims, CCL/CNI will undertake reasonable inquiry to ascertain the cause of such disparity and within ten business days of the completion of such inquiry will disclose to OIG and HCFA the results of such inquiry. If CCL/CNI determines that the disparity was caused by the use of basic chemistry profiles, CCL/CNI agrees to undertake any steps reasonably necessary to address the issue and will notify OIG of the steps the company plans to take. CCL/CNI agrees to make the supporting documentation underlying its calculations available to OIG upon request.

d. Notices to Clients.

(1) Pre-Revision Notice. Within six (6) months of the Execution Date of this Agreement, CCL/CNI agrees to provide each physician client a notice that, for each chemistry profile that includes a multi-channel chemistry test (e.g., 80002 - 80019) offered by CCL/CNI, sets forth (a) the individual components of the profile, (b) the CPT codes for the profile, (c) for Medicare, the National Limitation Amount for the test components in the profile, (d) for Medicaid, the maximum allowable reimbursement for the test components in the profile (if available), and (e) a description of how CCL/CNI will bill for each profile. CCL/CNI will, prior to issuance, provide a sample of such notice to OIG and HCFA.

(2) Post-Revision Notices. Once CCL/CNI has implemented its revised requisition forms as described in subparagraph 5.a., above, CCL/CNI will, on an annual basis, provide each client who has requested a customized profile with a notice that: (a) explains the Medicare and Medicaid reimbursement paid for each component of that profile, (b) encourages physicians who are ordering tests for which Medicare or Medicaid reimbursement will be sought to order only tests that are medically necessary for each patient, (c) warns the client that using a customized profile may result in the ordering of tests for which Medicare or Medicaid will deny payment, and (d) advises the client that the HHS OIG takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties.

(3) Physician Acknowledgments. CCL/CNI also agrees to continue to require a signed Physician Acknowledgment for all custom chemistry profiles set up for new clients and all new custom chemistry profiles set up for existing clients. The Physician Acknowledgment will state: (a) that when ordering tests for which Medicare or Medicaid reimbursement is sought, the physician should only order those tests which the physician believes are medically necessary for each patient, (b) that using a customized profile may result in the ordering of tests for which Medicare or Medicaid will deny payment, (c) that the physician should only order individual tests or a less inclusive profile where not all the tests in the customized profile are medically necessary for an individual patient, and (d) that HHS OIG takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties. The Physician Acknowledgments shall also include an acknowledgment by the physician of his/her awareness of the profile components and the Medicare and/or Medicaid reimbursement amounts for the tests in each customized profile. CCL/CNI agrees to provide OIG and HCFA a copy of the Physician Acknowledgment prior to its implementation, and to provide advance notice to OIG and HCFA and a copy of the new form when the Physician Acknowledgment is revised.

e. Retention of Information.

(1) Requisition Forms. CCL/CNI agrees to retain for the Term of this Agreement, either in original, electronic, microfilm or microfiche-type form, the requisition forms used by CCL/CNI during the Term of this Agreement. CCL/CNI agrees to make this information available for inspection by OIG or HCFA upon request.

(2) Compliance Pricing Guidelines. CCL/CNI represents that it is in the process of establishing basic compliance pricing guidelines applicable to all CCL/CNI patient list and monthly account list fee schedules. Under these guidelines, such fee schedules will reflect the value of each test listed in the respective marketplace, using basic value components that include both direct and indirect costs, as well as minimum profitability expectations. Compliance pricing guidelines will also include discounting guidelines applicable to overall accounts, profiles customized at the physicians request and at the individual test level. CCL/CNI agrees to provide OIG a copy of the compliance pricing guidelines no later than three months from the Execution Date of this Agreement, and to retain such guidelines (and any subsequent

changes made thereto) for the Term of this Agreement. CCL/CNI agrees that OIG is under no obligation to respond or comment on the compliance pricing guidelines.

f. Standardized Billing Process. CCL/CNI represents that it is moving to a national standardized billing process by which all laboratory billing will occur. A common information system has been selected for both laboratory and billing data and will be installed in all CCL/CNI facilities. Installation and related systems conversion will be prioritized by site on the basis of greatest need. CCL/CNI represents that the installation of common laboratory and billing information systems in all CCL/CNI facilities is a complex, time-consuming process which requires the highest level of technical skill in order to maintain the integrity of the data and avoid significant disruption to the normal business operations of CCL/CNI. CCL/CNI represents that it is undertaking this process in good faith and with the intention to complete it within a practicable time frame. Throughout this process, CCL/CNI agrees to continue to adhere to the internal audit protocol set forth in paragraph 21 of this Agreement. In addition, CCL/CNI will describe its progress in implementing the common laboratory and billing information systems in the Annual Report prepared pursuant to paragraphs 23 and 24 of this Agreement.

g. Sales and Marketing Personnel - Training. CCL/CNI represents that its sales and marketing employees annually receive the standard LCP training and education received by all CCL/CNI employees and described in paragraphs 17 and 18, including compliance training in the areas of sales and marketing. Such training focuses on the sales activities which are prohibited by Applicable Laws (as defined in paragraph 3), including, but not limited to, the offering of anything of value (remuneration) in return for the referral of business reimbursable in whole or in part by the Medicare and Medicaid programs. CCL/CNI agrees to require each CCL/CNI sales and marketing employee to sign an acknowledgment that he or she (1) has received training specific to sales and marketing and the prohibition against offering remuneration in return for referrals, (2) is aware that strict compliance with the CCL/CNI Standards of Conduct, LCP, and Applicable Laws, and, in particular, the prohibition against offering remuneration in return for referrals, is a condition of employment, and (3) is aware that CCL/CNI will take appropriate disciplinary action up to and including termination, for violation of the principles and practices set forth in the Standards of Conduct, the LCP, and Applicable Laws. CCL/CNI will maintain the certificates required by this provision and make them available to OIG upon request.

h. Discipline. CCL/CNI agrees to compile and maintain information on disciplinary actions taken against employees for violations of company policies related to the Applicable Laws. CCL/CNI will include in the Annual Report a summary of such disciplinary actions, which summary does not identify the individual or individuals disciplined.

i. Tests Not Reported or Performed. CCL/CNI represents that it has implemented systems changes and manual processes to help prevent and eliminate billing for tests not reported or performed ("TNRP") as to all payers at all CCL/CNI facilities. CCL/CNI agrees to continue those efforts:

(1) CCL/CNI compliance audit personnel will continue to perform a quarterly audit of every laboratory to ensure continued compliance. CCL/CNI represents that each laboratory has received on-site training on how to perform monthly audits, that TNRP activity is currently audited monthly by the local laboratory personnel, and that these monthly audits by local laboratory personnel will continue.

(2) As of the Execution Date of this Agreement, CCL/CNI represents that all laboratories have implemented a process to flag TNRPs in the laboratory's information system. CCL/CNI represents that training has been conducted to ensure that TNRPs are flagged properly, and that information technology personnel have audited the computer system of each CCL/CNI laboratory and programmed all TNRP flags (or messages) to convert properly to the laboratory's billing information system. The flagged accessions are suspended in the billing system until they can be manually reviewed, and accounts receivable personnel then manually review the accessions with TNRPs to ensure that TNRPs are not billed. CCL/CNI agrees that this process will continue, either on a manual or automated basis.

Corporate Integrity Program Management

6. Compliance Team. The CCL/CNI Compliance Team will continue to meet on a regular basis to discuss, approve, and oversee CCL/CNI's compliance activities. The Compliance Team is composed at this time of the following CCL/CNI employees: the Vice President and Chief Information Officer; the Vice President and Chief Financial Officer; the Vice President - Billing; a Regional Compliance Coordinator; the Vice President - Human Resources; the Vice President and Northeast Operations Leader; the Senior Vice President - Sales and Marketing; the Vice President - Internal Resources; the Vice President - NY/NJ Region Commercial Leader; the Vice President, Secretary and General Counsel; the Vice President - Compliance and Government Affairs; the Vice President and Central Region Operations Leader; the Vice President and Chief Compliance Officer; the Senior Vice President - Operations; and the Corporate Director of Reimbursement. A list of all current Compliance Team members is attached hereto as Exhibit A, and CCL/CNI agrees to update such list as necessary to reflect changes in position on the Compliance Team within a reasonable time of any such changes. CCL/CNI believes that each employee bears individual responsibility to ensure that his/her actions comply with this Agreement and all Applicable Laws. The CCL/CNI Compliance Team shall have ultimate responsibility for ensuring CCL/CNI's compliance with this Agreement and all Applicable Laws.

7. Compliance Department. The Compliance Department, headed by the Vice President - Compliance and Government Affairs, is responsible for monitoring the compliance of all CCL/CNI employees with this Agreement, the LCP, the Standards of Conduct set forth in the CCL/CNI Corporate Compliance Manual, and all Applicable Laws. The Compliance Department will continue to conduct audits and investigations and prepare written reports as required by this Agreement. The Compliance Department, with the approval and oversight of the Compliance Team, promulgates and communicates compliance policies throughout CCL/CNI.

8. Vice President - Compliance and Government Affairs. The Vice President - Compliance - Government Affairs leads the Compliance Department in achieving and maintaining compliance with Applicable Laws throughout the CCL/CNI laboratory network. The following individuals report to the Vice President of Compliance and Government Affairs on compliance related matters: the Chief Compliance Officer, the Corporate Director of Reimbursement, the Director of Corporate Compliance, and the Director of State Government Affairs. A copy of the job description of the Vice President - Compliance and Government Affairs is attached as Exhibit B.

9. Chief Compliance Officer. The Chief Compliance Officer works with and at the direction of the CCL/CNI Compliance Team to establish, maintain and revise corporate compliance policies and procedures and to ensure that all CCL/CNI operations are conducted in compliance with Applicable Laws, as well as state laws and regulations. A copy of the job description of the Chief Compliance Officer is attached as Exhibit C.

10. Corporate Director of Reimbursement. The Corporate Director of Reimbursement works with reimbursement specialists and auditors to ensure CCL/CNI compliance with Applicable Laws. The Corporate Director of Reimbursement and his/her staff perform comprehensive compliance audits, CPT audits, TNRP audits, "no test requested" ("NTR") audits, and due diligence audits, and approve all marketing materials such as requisitions, fee schedules, and laboratory reference manuals. A copy of the job description of the Corporate Director of Reimbursement is attached as Exhibit D.

11. Director of Corporate Compliance Operations. The Director of Corporate Compliance Operations serves as the primary Compliance Department contact and resource for the 23 Regional Compliance Coordinators located throughout the CCL/CNI laboratory network. The Director of Corporate Compliance Operations facilitates the implementation of Corporate Compliance initiatives, including coordinating training and other activities among regional compliance coordinators and tracking and analyzing various compliance related scores and trends for management review and guidance. A copy of the job description of the Director of Corporate Compliance Operations is attached as Exhibit E.

12. Regional Compliance Coordinators. The Regional Compliance Coordinators act as a liaison between the regional laboratories and the Compliance Department. These individuals are responsible for keeping the Compliance Department informed of compliance activities in the region and for maintaining and distributing CCL/CNI policies and compliance bulletins to employees throughout the regions. The Regional Compliance Coordinators also assist at the regional level with on-site training sessions, gather information and prepare monthly reports regarding new or changed compensation relationships with physicians and physician-owned entities, monitor the status of and assist with third-party payor audits upon request of the Compliance Department, assist in implementing changes on a local level in test requisitions, fee schedules, reference manuals, etc., as directed by the Compliance Department, monitor continued adherence to compliance policy, procedure and programs at

the regional level, and perform such other compliance related duties as may be assigned by the Compliance Department. A copy of the job description of the Regional Compliance Coordinators is attached as Exhibit F.

Compliance Policies and Standards of Conduct

13. CCL/CNI agrees to continue to establish compliance procedures and policies to be codified in a CCL/CNI Corporate Compliance Policy Manual ("Corporate Compliance Policy Manual" or "Manual"). A copy of the Manual will be provided to OIG within three (3) months of the Execution Date of this Agreement. CCL/CNI compliance personnel, at their discretion and as necessary, will consult with HCFA and the Medicare carriers when developing policies and procedures relating to the submission of Medicare claims. CCL/CNI also agrees to continue to maintain Standards of Conduct so as to ensure that CCL/CNI and each of its directors, officers, employees, and those individuals engaged directly by CCL/CNI as independent contractors involved in the sale, marketing, ordering or billing of lab services, maintain the business honesty and integrity required of a Medicare and Medicaid supplier, and that CCL/CNI's conduct is in strict compliance with Applicable Laws.

Annual Certifications

14. The Corporate Compliance Manual will be circulated and/or made available to all CCL/CNI employees either via hard copy or, where available, computer transmission. Employees will be required to review the policies in the Manual and to certify their review as set forth below:

a. Employees: Within 180 days of the Manual being finalized, each person involved in the sale, marketing, or billing of laboratory services, and all phlebotomists and other individuals involved in the ordering of laboratory services, will: (1) receive and review those policies in the Manual applicable to such person's job performance, (2) discuss with his/her supervisor or the supervisor's designee the Standards of Conduct set forth in those policies, and (3) sign an acknowledgment that he/she has complied with (1) and (2) above and will abide by those policies. Thereafter, within sixty (60) days of starting employment with CCL/CNI, new employees involved in the sale, marketing or billing of laboratory services, and all new phlebotomists and other individuals involved in the ordering of laboratory services, will also fulfill the requirements set forth in (1), (2), and (3) above. In years subsequent to the initial certification, each then-current employee involved in the sale, marketing or billing of laboratory services, and all phlebotomists and other individuals involved in the ordering of laboratory services, shall annually repeat the procedure of reviewing those policies in the Corporate Compliance Manual applicable to that employee's job and shall sign a new acknowledgment. CCL/CNI will maintain the acknowledgments required by this provision and make them available to OIG upon request.

b. Managers and Supervisors: Promotion of and adherence to this Agreement, the LCP, the CCL/CNI Standards of Conduct, and the procedures and policies contained in the Corporate Compliance Manual shall be an element of the performance evaluation of each manager and supervisor. In addition to signing their own employee acknowledgments as required in subsection a., above, all managers and supervisors involved in the sale, marketing, or billing of laboratory services and all managers and supervisors who oversee phlebotomists also will attest that they or their designee has: (1) discussed with each employee under their supervision the content and application of the LCP, the Standards of Conduct, and the policies and procedures found in the Corporate Compliance Manual applicable to that employee's job; (2) informed each such employee that strict compliance with the Standards of Conduct, the LCP, and the policies and procedures contained in the Corporate Compliance Manual is a condition of employment; and (3) informed each such employee that CCL/CNI will take disciplinary action up to and including termination, for violation of CCL/CNI's policies and procedures, as well as the Applicable Laws. CCL/CNI will maintain the certificates required by this provision and make them available to OIG upon request.

c. Chief Compliance Officer: CCL/CNI shall submit, as part of each Annual Report to OIG pursuant to Paragraphs 23 and 24, a statement by the Chief Compliance Officer that he/she has verified (1) that the signed acknowledgments and certifications described above are being maintained, (2) that to the best of his/her knowledge based on reasonable inquiry, each employee involved in the sale, marketing, or billing of laboratory services, and each phlebotomist or other individual involved in the ordering of laboratory services, has signed the acknowledgments as required by this provision, and (3) that to the best of his/her knowledge based on reasonable inquiry, each manager and supervisor has signed the certifications as required by this provision.

Notice to Employees

15. CCL/CNI agrees to post in common work areas in its laboratory locations a Notice (form of Notice to be submitted to OIG in advance of posting) that details CCL/CNI's commitment to comply with all Applicable Laws in the conduct of its business. Such Notice will be placed in a prominent place accessible to employees.

Hot Line

16. CCL/CNI has established and agrees to maintain a "Hot Line" telephone number for reporting suspected misconduct to the Compliance Department. CCL/CNI agrees to post a "Hot Line" notice in common work areas in each of its laboratories identifying the telephone number to be used for such reporting. As part of the Annual Reports required by paragraphs 23 and 24, CCL/CNI shall provide a list of the number and type of all calls made to the "Hot Line" during the previous year. With respect to any "Hot Line" calls that allege possible violations of the Applicable Laws which may have a material impact on the Medicare and/or State health care programs, CCL/CNI shall include information on the nature of the

allegations, a description of the action taken in response, the results of any internal investigation, and a description of any corrective action taken by CCL/CNI, other than information identifying the individuals involved. Matters pending resolution at the time of the Annual Report period shall continue to be listed in subsequent Annual Reports until final resolution of the matter is reported.

Training and Education

17. CCL/CNI has instituted and will maintain an ongoing training and education program designed to ensure that each employee is aware of and understands the Applicable Laws, the LCP, the Standards of Conduct, and his or her duty to ensure compliance with the same. Upon the Execution Date of this Agreement, CCL/CNI agrees that such training and education will include notifying all CCL/CNI employees of the fact and substance of this Agreement and the importance of each employee's abiding by the terms of this Agreement, all Applicable Laws, and CCL/CNI policies and procedures. Such training and education will contain information on the potential consequences both to the employee and to CCL/CNI of any failure to achieve and maintain compliance with this Agreement, Applicable Laws, the LCP, the Standards of Conduct, and the policies set forth in the Compliance Manual, including the range of disciplinary actions that may be taken in the event of such a failure.

18. Each person covered by the LCP currently receives at least four (4) hours of initial training regarding the LCP. New employees receive such training within 120 days of joining CCL/CNI. CCL/CNI agrees that, thereafter, each employee shall receive not less than one (1) additional hour of supplemental training regarding the LCP annually. As part of this training, employees will be advised that compliance is a condition of their employment. A schedule and subject outline for the training and education program shall be maintained by CCL/CNI and shall be provided to OIG upon request. CCL/CNI agrees to continue these efforts.

Limitations on Hiring

19. CCL/CNI agrees that it shall not employ, enter into an independent contractor services contract with, or otherwise use the services of any individual whom CCL/CNI knows or should have known, after reasonable inquiry, (a) has been convicted of a criminal offense related to health care, or (b) is currently listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in federally funded health care programs. In furtherance of this requirement, CCL/CNI agrees to make reasonable inquiry as to any individual who is a prospective employee, agent, or individual considered for engagement directly by CCL/CNI as an independent contractor by reviewing the General Services Administration's List of Parties Excluded from Federal Programs and HHS/OIG Cumulative Sanction Report. CCL/CNI shall not be required to terminate the employment of individuals who are charged with a criminal offense related to health care, or proposed for debarment or exclusion during their employment with CCL/CNI, provided, however, that CCL/CNI will immediately remove such

employees from direct responsibility for or involvement in any federally funded health care program until the resolution of such criminal charges or proposed debarment or exclusion. If the individual is subsequently convicted, debarred or excluded, CCL/CNI will terminate its employment relationship and/or affiliation with that individual. CCL/CNI shall notify OIG of each such personnel action taken, and the reasons therefor, within thirty (30) days of the action. For purposes of this Agreement, the term "convicted" shall have the meaning given in the Medicare Statute, 42 U.S.C. Section 1320a-7(i).

CCL/CNI Compliance Activities

20. Compliance Activities. CCL/CNI will, on an on-going basis, continue to engage in compliance activities, including conducting regular audits of its laboratories for compliance with Applicable Laws and CCL/CNI's policies as set forth in the Compliance Manual and reviewing its billing policies, procedures and practices to ensure that federally funded health care programs are billed appropriately for services rendered. CCL/CNI shall include in the Annual Report required by paragraphs 23 and 24 a description of its efforts in this regard during the previous year and the results of those efforts.

21. Audits. As part of its regular compliance activities, CCL/CNI agrees to continue, on a biennial basis, to audit all of its regional laboratories for a broad range of legal and reimbursement compliance issues. These legal and reimbursement audit issues shall at a minimum include the following: (a) state law and regulatory issues, (b) contract/agreement issues, (c) competitive practices issues, (d) marketing materials issues, (e) CPT coding and billing issues, (f) test information and reporting issues, and (g) record keeping issues. These audits shall be performed in accordance with the comprehensive audit procedures that are currently being used by the CCL/CNI Compliance Department. These on-site company-wide audits shall continue to consider legal issues and company policies that are contained in the Corporate Compliance Manual. They will continue to include onsite visits and interviews with local management, operations, billing, sales, and other appropriate personnel. They will also continue to include a review of written materials and documentation that are used by the laboratory. The Compliance Department will continue to prepare comprehensive audit reports based on its findings which will be made available to the Compliance Team and the Operations Leader of the audited facility. Appropriate cornpliance, legal, and local business personnel will then discuss and document implementation and follow-up of all needed corrective action. CCL/CNI shall include in the Annual Report required by paragraphs 23 and 24 a description of its audit activities and the results thereof. CCL/CNI will make any supporting work papers and background information available to OIG upon request.

22. Duty to Investigate, Report and Correct.

a. If, (1) in performing the compliance activities and audits described in paragraphs 20 and 21, above, or (2) CCL/CNI receives from any other source credible evidence of employee misconduct, CCL/CNI determines that there are reasonable grounds to

suspect that a material violation of either (a) Applicable Laws, (b) this Agreement, or (c) CCL/CNI's Standards of Conduct or policies contained in the Corporate Compliance Manual has occurred, CCL/CNI will conduct an appropriate internal inquiry/investigation. CCL/CNI will make the initial determination of whether there are reasonable grounds to conclude that a material violation of the Applicable Laws governing federally funded health care programs occurred.

b. If, at the conclusion of the internal inquiry/investigation, CCL/CNI identifies an overpayment amount owed to a federally funded health care program but determines there are no grounds to conclude that a material violation of Applicable Laws, this Agreement, or CCL/CNI's Standards of Conduct or policies contained in the Corporate Compliance Manual occurred, CCL/CNI shall immediately undertake appropriate corrective actions to eliminate the cause of the overpayments and shall make prompt restitution of the overpayment amount to the appropriate federally funded health care program pursuant to a process agreed upon by the HCFA Bureau of Program Operations. CCL also will report in the Annual Report: (1) the cause of the overpayment, (2) the calculation of the overpayment, (3) CCL/CNI's actions to correct the cause of the overpayment, and (4) any further steps CCL/CNI plans to take to address the cause of the overpayment and prevent it from recurring in the future.

c. If, at the conclusion of the internal inquiry/investigation, CCL/CNI determines there are reasonable grounds to conclude that a material violation of Applicable Laws, this Agreement, or CCL/CNI's Standards of Conduct or policies contained in the Corporate Compliance Manual did occur, CCL/CNI shall immediately undertake appropriate corrective actions, including prompt restitution of any overpayments to federally funded health care programs, pursuant to a process agreed upon by the HCFA Bureau of Program Operations, to the extent that CCL/CNI is legally responsible for any such overpayments. CCL/CNI also will report promptly to the addressee in the OIG Office of Enforcement and Compliance as required by paragraph 42: (1) its findings concerning the material violation, (2) the calculation of any overpayment, when necessary, (3) CCL/CNI's actions to correct such material violation, and (4) any further steps CCL/CNI plans to take to address such material violation and prevent it from recurring in the future.

d. If CCL/CNI receives a final written report issued by an agency or organization charged with reviewing compliance with applicable licensure, accreditation, and/or certification requirements, which finds significant deficiencies relative to such requirements, CCL/CNI shall promptly take steps to correct such deficiencies to the reasonable satisfaction of the agency or organization, and will provide OIG with a copy of the final written report issued by the agency or organization and a description of any corrective steps taken.

e. The Annual Report shall include a list and summary description, for the preceding year, of (1) all internal inquiries/investigations conducted pursuant to paragraph

22.a., including any where CCL/CNI determined there were not reasonable grounds to believe that a material violation of Applicable Laws, this Agreement, or CCL/CNI's Corporate Integrity Program occurred, and (2) all reports made pursuant to paragraph 22.c.

Annual Reports

23. CCL/CNI will annually submit a report (the "Annual Report") to OIG describing the measures taken by CCL/CNI to implement and to ensure compliance with this Agreement. The first such report shall cover the period October 1 through December 31, 1996, and shall be submitted no later than March 1, 1997. Such first Annual Report shall detail CCL/CNI's plans for complying with this Agreement. All subsequent Annual Reports shall be submitted no later than April 1 of the relevant year, beginning April 1, 1998 for the 1997 calendar year, and concluding with the last such report due April 1, 2002 for the calendar year 2001.

24. The Annual Report (other than the report due March 1, 1997) shall include, among other things, the following:

a. A summary of the actions taken during the preceding twelve (12) months to comply with the terms of this Agreement, as well as Applicable Laws;

b. A list of the documents, notices, instructions, and reports prepared by or for CCL/CNI during the preceding year to ensure compliance with this Agreement, as well as Applicable Laws;

c. A narrative of the methods used and identification of the individuals involved in verifying compliance;

d. The status of any ongoing governmental investigation of CCL/CNI involving possible violations of Applicable Laws;

e. Verification that all applicable employees have signed the certification statement described in paragraph 14 and received the applicable compliance training described in paragraphs 17 and 18, and verification that marketing and sales personnel have completed the certifications described in paragraph 5.g.;

f. Copies of the schedules and topic outlines for the training and education programs;

g. Certification by the Vice President - Compliance and Government Affairs, in accordance with 28 U.S.C. section 1746, that, to the best of his/her knowledge, CCL/CNI is in compliance with the terms of this Agreement, except as noted in accordance with subparagraph 24.h., below;

h. A summary of the status and resolution of any internal investigation reported to OIG pursuant to paragraph 22;

i. Any substantive changes in the directives, instructions, or procedures for implementation of the Corporate Integrity Program;

j. A list of the number and type of all calls made to the company Hot Line within the previous year, including the information required under paragraph 16;

k. A list of all investigations of alleged violations or misconduct performed pursuant to paragraph 22 during the preceding year;

l. A summary of all disciplinary actions taken against employees for violations of CCL/CNI Standards of Conduct or policies contained in the Corporate Compliance Manual and related to the Applicable Laws, as required by subparagraph 5.h.; and

m. Any other documents or reports required by this Agreement and not specifically enumerated in this paragraph.

25. If, after receipt of the Annual Report, OIG has reason to believe that compliance with this Agreement and Applicable Laws is not sufficiently evidenced by the Annual Report, either because (a) OIG reasonably believes there is inadequate documentation of such compliance or (b) OIG reasonably believes there is material non-compliance with the Agreement or Applicable Laws, OIG shall notify CCL/CNI in writing of the reasons for its belief and CCL/CNI will be given the opportunity to conduct reasonable reviews and/or evaluations and to provide such additional information and documentation as may reasonably be required by OIG to verify the representations in the Annual Report and compliance with the Agreement and with all Applicable Laws. In the event that OIG reasonably determines that CCL/CNI is still not in material compliance after receipt of the additional information and documentation, OIG, at its option, may, at CCL/CNI's expense: (1) conduct an audit and review, (2) retain independent professionals to conduct a third-party audit and review, or (3) require the CCL/CNI to retain independent professionals to audit and review where appropriate.

Other Reports to OIG

26. In addition to the periodic written reports required herein, CCL/CNI shall notify OIG within ten business days of the time CCL/CNI corporate headquarters receives notice of (a) the initiation of any criminal, civil or administrative investigation of CCL/CNI by any governmental entity, (b) receipt of subpoenas by CCL/CNI from any state or federal governmental entity, (c) receipt of search warrants by CCL/CNI and/or searches carried out in any CCL/CNI facility, or (d) the disposition of legal action against CCL/CNI that reflects on CCL/CNI's ability to adequately provide services to Medicare and/or Medicaid beneficiaries,

but only to the extent that any such investigation, subpoena, search warrant or search, or disposition of a legal action described herein in subparagraphs (a) through (d) involves the possible violation of the Applicable Laws by CCL/CNI. CCL/CNI shall provide to OIG as much information as is reasonably necessary to allow OIG to determine the impact of the investigative or legal activity upon the present responsibility of CCL/CNI to continue as a Medicare and Medicaid supplier.

Diagnostic Information

27. The term "limited coverage policy" as used herein shall mean that the insurance carrier administering a federally funded health insurance program ("Carrier") or single State agency has decided to limit program coverage of certain clinical tests to situations where the tests were ordered and performed due to a set of pre-determined diagnoses. In regions where the Carrier or State have implemented a limited coverage policy for particular tests, CCL/CNI will submit to the Carrier or State diagnostic information obtained exclusively from the ordering physician; provided, however, that nothing in this paragraph precludes CCL/CNI: (a) from contacting the ordering physician's office staff to obtain diagnostic information in the event that the physician has failed to provide such information to CCL/CNI; (b) from providing services pursuant to a standing order executed in connection with an extended course of treatment; or, (c) from accurately translating narrative diagnoses obtained from the physician to ICD-9 codes. CCL/CNI will document all such follow-up contacts and make such documentation available to OIG upon request.

28. In implementing the provisions of paragraph 27, CCL/CNI will continue to train its employees regarding CCL/CNI's policies against using diagnostic information obtained from anyone other than the ordering physician or his/her legally authorized designee. However, as stated in paragraph 27 above, nothing in this Agreement precludes CCL/CNI from assigning diagnostic codes for tests performed pursuant to medically appropriate standing orders executed in connection with an extended course of treatment. Consistent with State law requirements, CCL/CNI will: (a) contact each nursing home where it relies upon standing orders executed in connection with an extended course of treatment to confirm in writing the continued validity of all current standing orders; and (b) will verify standing orders relied upon at draw stations with the physician, physician's office staff, or such other persons authorized by law. With respect to ESRD patients, at least once a year CCL/CNI will contact each ESRD facility or unit to request confirmation in writing of the continued validity of all current standing orders.

Sale of a Laboratory

29. In the event that CCL/CNI enters into a signed agreement, for example, a binding Letter of Intent, to sell or transfer ownership of any of its laboratories, CCL/CNI shall notify OIG promptly after the execution of such agreement by all parties thereto.

a. Upon closing any such sale or transfer of any of its laboratories, CCL/CNI shall refrain from the use of all Medicare and Medicaid provider numbers assigned to any laboratory sold or transferred except in compliance with Medicare and Medicaid program requirements.

b. No later than thirty (30) days prior to the scheduled closing for the sale or transfer of any laboratory, CCL/CNI will transmit to OIG: (1) the cumulative information already gathered at that time by CCL/CNI with respect to such laboratory that otherwise CCL/CNI would be required to include in its next Annual Report; (2) a listing of all provider numbers under which services performed by that laboratory were billed to the Medicare and/or Medicaid programs, together with a statement regarding the anticipated post-closing use of such numbers; and (3) a listing of corrective compliance actions undertaken by CCL/CNI with respect to that facility and previously reported pursuant to this Agreement. In the event that the scheduled Closing is within 45 days of the date of the most recent Annual Report, no report pursuant to this subsection b. shall be required.

Closing and Name Changes

30. A CCL/CNI laboratory will be closed within the meaning of this paragraph when it ceases using both the CCL/CNI requisition form and any provider number presently used by CCL/CNI. The closing of a CCL/CNI laboratory shall exclude a sale or transfer within the meaning of paragraph 29. CCL/CNI will notify OIG at least thirty (30) days in advance of such closing and will both disclose all provider numbers used by that laboratory and advise OIG regarding any plans to use those provider numbers in the future. In the event that all CCL/CNI laboratories are closed as defined in this paragraph, this Agreement will be suspended and cease to have any force and effect at such time as CCL/CNI ceases all use of any and all provider numbers presently used by it. In the event that CCL/CNI reopens any or all laboratories, this Agreement will be reactivated and remain in force and effect through the end of the Term of this Agreement.

31. In the event that a CCL/CNI laboratory undergoes a name change, for business or internal organizational reasons, but is not closed as defined in paragraph 30 above, CCL/CNI will notify OIG in advance of such name change, and all provisions of this Agreement will remain in force and effect, except that such name change will not constitute a sale or transfer within the meaning of paragraph 29.

Applicability to New Labs

32. CCL/CNI will advise OIG of any purchase by CCL/CNI of a new clinical laboratory or a company which owns any clinical laboratories within thirty (30) days of the closing of such transaction. In the event that CCL/CNI purchases a new clinical laboratory or a company which owns any clinical laboratories, CCL/CNI shall implement all applicable provisions of this Agreement, including any training or education requirements, within 180

days following such purchase or by such later date as agreed to by OIG, such agreement not to be unreasonably withheld.

Retention of Records

33. CCL/CNI will maintain any reports and certifications specifically required by this Agreement for a period of six (6) years from creation of those reports and certifications. CCL/CNI will maintain all other documentation specifically required by this Agreement, either in original, electronic, microfilm or microfiche-type form, for a period of six (6) years from its creation, and upon request will provide copies to OIG within a reasonable period of time.

34. CCL/CNI shall maintain written reports and minutes of any and all CCL/CNI Board meetings reflecting the reports made to the CCL/CNI Board by the Vice President - Compliance and Government Affairs and/or the Chief Executive Officer of CCL/CNI and the CCL/CNI Board's decisions or directions concerning matters related to the LCP or this Agreement, and upon request will provide to OIG within a reasonable period of time copies of those portions of such reports or minutes that concern matters related to compliance with Applicable Laws, the LCP, or this Agreement.

OIG Right to Inspect

35. In addition to any other right OIG may have by statute, regulation, or contract, upon reasonable notice, OIG or any duly authorized representatives may examine at CCL/CNI's place of business CCL/CNI's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating CCL/CNI's compliance with the terms of this Agreement and Applicable Laws. OIG also shall be entitled upon reasonable notice to inspect all records required to be generated and maintained as part of this Agreement, and OIG shall be allowed to copy such documents and retain any such copies or request, receive and retain copies of such documents from CCL/CNI. The materials described above shall be made available by CCL/CNI at all reasonable times for inspection, audit, or reproduction. Further, for purposes of this provision, upon reasonable notice, OIG or any duly authorized representatives may interview any CCL/CNI employee who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed between the employee and OIG. Each employee shall be advised by OIG or any duly authorized representative prior to any such interview that the employee may elect to be interviewed with or without a representative of CCL/CNI present. The decision of any employee not to be interviewed by any government representative shall not be deemed a breach of this Agreement.

Notice to OIG Regarding CCL/CNI Management

36. Within thirty (30) days of the Execution Date of this Agreement, CCL/CNI will submit a list of the principal members of CCL/CNI Management responsible for compliance,

including the identities of the members of the Compliance Team and the Compliance Department, the Chief Compliance Officer, the Corporate Compliance Coordinator, and the Regional Compliance Coordinators. CCL/CNI agrees to update such list(s) as necessary and within a reasonable period of time to reflect changes in position or identity of management personnel responsible for compliance.

Notice to OIG Regarding Corporate Executive Officers

37. Within thirty (30) days of the Execution Date of this Agreement, CCL/CNI will submit a list of its corporate executive officers and directors to OIG. CCL/CNI will notify OIG of any changes in the position or identity of its corporate executive officers and directors within a reasonable time.

Material Breach: Notice and Opportunity to Cure

38. In the event that OIG believes that CCL/CNI is in material breach of one or more of its obligations under this Agreement, OIG shall give CCL/CNI written notice by certified mail specifying the nature and extent of the alleged breach. CCL/CNI will have thirty (30) days from receipt of the notice: (a) to fully cure the breach; or (b) otherwise satisfy OIG that (1) it is in compliance with the Agreement or (2) that the breach cannot be reasonably cured within 30 days, but that CCL/CNI has commenced action to cure the breach and is pursuing such action with diligence.

Exclusion or Suspension from Programs

39. If, notwithstanding CCL/CNI's efforts to cure or otherwise satisfy OIG pursuant to paragraph 38, OIG continues to believe that CCL/CNI is in material breach of any provision of the Agreement, OIG may, through its Office of Inspector General, declare CCL/CNI to be in default of this Agreement and may seek to exclude or suspend CCL/CNI from participation in the Title XVIII (Medicare) program, Title XIX (Medicaid) program, and other state health care programs, as defined in 42 U.S.C. section 1320a-7(h), until such time as CCL/CNI has fully cured such material breach or otherwise satisfied OIG in accordance with paragraph 38 (above). In the event that CCL/CNI fully cures the material breach or otherwise satisfies OIG, it will be promptly reinstated, retroactive to the date of cure.

40. An exclusion pursuant to paragraph 39 of this Agreement shall be deemed an exclusion pursuant to 42 U.S.C. Section 1320a-7(b)(7). Upon notification by OIG of its intent to exclude or suspend CCL/CNI from participation, CCL/CNI is entitled to pre-exclusion due process as afforded a provider under 42 U.S.C. Section 1320a-7(f), including judicial review pursuant to 42 U.S.C. Sections 405(g) and 1320a-7(f), or other applicable statute. Notwithstanding any provision of Title 42 of the Untied States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion or suspension based on the material breach of this Agreement shall be: (a) whether CCL/CNI was in material

breach of one or more of its obligations under this Agreement at the time of and as specified in the notice given to CCL/CNI; (b) whether such material breach was continuing on the date on which OIG notified CCL/CNI of its proposal to exclude; and (c) whether CCL/CNI failed to cure the material breach or otherwise satisfy OIG within thirty (30) days after receiving notice thereof from OIG. OIG shall bear the burden of proof in such proceedings.

41. Subsequent to a final decision to exclude or suspend CCL/CNI, CCL/CNI retains the right to apply for reinstatement under 42 C.F.R. sections 1001.3001-1001.3004. The parties further agree that the procedures governing administrative review of OIG's determination to seek exclusion or suspension, as set forth by 42 C.F.R. Parts 1001 and 1005, are applicable, except that OIG shall bear the burden of proof in such proceedings.

Notices Required Hereunder

42. Any notices or information required hereunder shall be in writing and delivered or mailed by registered or certified mail, postage prepaid, as follows:

If to CCL/CNI, to:
Carolyn Kim McCarthy
Vice President - Compliance and Government Affairs
Corning Clinical Laboratories, Inc.
1350 I Street, NW Suite 500
Washington, D.C. 20005-3305

cc:
Raymond C. Marier
Vice President and General Counsel
Corning Clinical Laboratories, Inc.
One Malcolm Avenue
Teterboro, New Jersey 07608

If to OIG, to:
Eileen T. Boyd, Esq.
Deputy Inspector General
Office of Enforcement and Compliance
Department of Health and Human Services
330 Independence Ave. SW, Room 5600
Washington, D.C. 20201

If to HCFA, to:
Linda Ruiz, Director
Office of Benefits Integrity
Mail Stop S3-02-26
7500 Security Boulevard
Baltimore, Maryland 21207

Costs

43. CCL/CNI agrees that all costs, as defined in FAR 31.205-47, incurred on behalf of CCL/CNI current or former officers or directors arising from, related to, or in connection with the Government's civil and criminal investigations, CCL/CNI's defense and settlement thereof, the Civil Settlement Agreement entered into by CCL/CNI and the United States, or the performance or administration of this Agreement, shall be unallowable for Medicare, Medicaid, or other Government contract accounting purposes. CCL/CNI agrees to account separately for such costs. CCL/CNI shall treat these costs as unallowable costs for Government contract accounting purposes and shall account separately for such costs. Included in these unallowable costs are any legal or related costs expended on behalf of any convicted CCL/CNI employee. CCL/CNI also agrees to treat as unallowable the full salary and benefits costs of any officer, employee, or consultant removed from government contracting in accordance with the CCL/CNI policy regarding employees who are indicted, debarred, suspended, or proposed for debarment, and the cost of any severance payments or early retirement incentive payments paid to employees released from the company as a result of the wrongdoing at issue here.

Privileges Maintained

44. CCL/CNI contends that the attorney-client privilege and the attorney work-product doctrine may attach to certain information, documents, communications, and notes, memoranda, recordings, or detailed descriptions of interviews, or other information related to the subject matter of this Agreement. CCL/CNI presently intends to preserve this privilege and doctrine to the extent permitted by law, and OIG recognizes that CCL/CNI may assert them, to the extent they may exist. Nothing in this Agreement shall be construed to require the production of material protected by such privilege and/or doctrine, except that CCL/CNI agrees that it shall not assert the privilege and/or doctrine as a basis for withholding any audits, audit work papers, supporting exhibits or analytical documents supporting such audit, with respect to any audit performed pursuant to this Agreement to determine the overpayment from or cost impact to federally funded health care programs of CCL/CNI billings. OIG reserves the right to contest the asserted applicability of the privilege and/or doctrine in any given instance. Nothing in the Agreement, including the submission of reports, documents or other information pursuant to this Agreement, is intended as, constitutes, or shall be construed as a waiver of CCL/CNI's attorney-client, work-product, or other privileges and rights, including rights it may have under the Freedom of Information Act. OIG specifically agrees that it will not contend that CCL/CNI's production of any reports or their underlying documents, or the furnishing of additional information relating to this Agreement, constitutes a waiver of the attorney-client privilege and work-product doctrine as may be applicable.

Confidentiality

45. The confidentiality of all documents and other information provided by CCL/CNI in connection with its obligations under this Agreement shall be maintained by OIG except to the extent disclosure is required by law. Nothing in this Agreement shall be construed to prohibit OIG from providing information to any other department or agency of the United States Government or of any State charged with enforcing the laws against health care fraud if the information relates to matters within the department's or agency's jurisdiction, provided that any such entity receiving such information shall be advised by OIG of the confidentiality provisions of this Agreement. OIG agrees that certain information submitted to it under this Agreement may constitute trade secrets or confidential commercial or financial information within the meaning of section 552(b) of the Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552(b)(4). Since OIG has determined that such records may fall under this exemption, OIG further agrees to follow its pre-disclosure notification procedures set out in 45 C.F.R. Section 5.65. These procedures include prior notice to CCL/CNI of any potential release of records under the FOIA and an opportunity to provide information as to why the information is exempt under 5 U.S.C. Section 552(b)(4). CCL/CNI will also be given advance notice if OIG decides that any such information is not exempt under section 552(b)(4).

46. This Agreement does not constitute, and shall not be construed as, an admission by any person or entity, with respect to any issue of law or fact. The performance under this Agreement of any of the obligations of CCL/CNI, including the submission of documents and reports required by this Agreement, does not constitute, and shall not be construed as, an admission by any person or entity, with respect to any issue of law or fact.

Modifications

47. This Agreement may not be changed, altered or modified, except in writing signed by all parties.

Definitions

48. For purposes of this Agreement, the following definitions will apply:

a. General Requisition Form. A general requisition form is one which presents the noncustomized test offerings of the laboratory.

b. Customized Profile. A customized profile is a selection of tests grouped together at the request of the referring physician and which can be ordered as a group, rather than separately.

c. Applicable Laws. Title XVIII of the Social Security Act, 42 U.S.C. Sections 1395-1395ccc (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. Sections 1396 et seq. (the Medicaid statute); the Medicare Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b); the False Claims Act, 31 U.S.C. Sections 3729 et seq. (as amended); the Program Fraud Civil Remedies Act, 31 U.S.C. Sections 3801 et seq.; the federal Anti-Kickback Act, 42 U.S.C. Sections 52 et seq.; and the Civil Monetary Penalties Law, 42 U.S.C. Sections 1320a-7a and 1320a-7b; and all applicable implementing regulations.

d. Material Violation. A material violation is one which: (1) has, or has the potential to have, a significant, adverse financial impact on the Medicare and/or Medicaid programs; (2) is a systemic failure to comply with Applicable Laws, the LCP, this Agreement, the Standards of Conduct, or the policies or procedures contained in the Corporate Compliance Manual, regardless of financial impact on the Medicare and/or Medicaid programs; or (3) has an adverse effect on the quality of care provided to program beneficiaries.

e. Material Breach. A material breach means a failure to abide by a significant term of this Agreement.

f. Convicted. The term convicted shall have the meaning given in the Medicare Statute, 42 U.S.C. Section 1320a-7(i): " . . . an individual or entity is considered to have been 'convicted' of a criminal offense -- (1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged; (2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court; (3) when a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court; or (4) when the individual or entity has entered into participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld."

g. Annual Report. The Annual Report is a yearly report describing the CCL/CNI compliance activities conducted during the previous calendar year and the findings resulting from those activities. The Annual Report contains all of the summaries, descriptions, reports, and supporting documentation (where appropriate) required of CCL/CNI by this Agreement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dated: 10/9/96

By: _____
Lewis Morris
Assistant Inspector General
for Legal Affairs
Office of Inspector General
United States Department of
Health and Human Services

CORNING CLINICAL LABORATORIES, INC.

Dated: 10/9/96

By: _____
Kenneth W. Freeman
Chairman, President, and
Chief Executive Officer
Corning Clinical Laboratories, Inc.

Dated: 10/9/96

By: _____
Carolyn Kim McCarthy
Vice President - Compliance and
Government Affairs
Corning Clinical Laboratories, Inc.